INTERNATIONAL SEARCHING AUTHORITY

To: PAUL BIANCO
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	29 APR 2010

Applicant's or agent's file reference	FOR FURTHER ACTION
782-P10-048	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/025263	24 February 2010	24 February 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/08 (2010.01)
USPC - 606/213

Applicant P TECH, LLC

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450	13 April 2010	Blaine R. Copenheaver
Facsimile No. 571-273-3201		PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (July 2009)

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	61, 67	YES
	Claims	1-60, 62-66, 68-71	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-71	NO
Industrial applicability (IA)	Claims	1-71	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-60, 62-66 and 68-71 lack novelty under PCT Article 33(2) as being anticipated by Bonutti et al., (Hereinafter referred to as "Bonutti").

Referring to claim 1, Bonutti discloses a method of utilizing a bondable material (802 and 850; Figs. 34 and 38) to position a fastening implant (840 in conjunction with 800; 2034 and 2006; Figs. 33 and 55-56) in a body (882; Paras. [0447-0451]), said method comprising the steps of: engaging an end effector (804; Fig. 33) and at least a trailing end (the end near element 810; Fig. 33) of the fastening implant (Fig. 34); passing at least a portion of the end effector and the fastening implant into the body (Figs. 34 and 40A); positioning at least a leading end (the end near element 820; Fig. 33) of the fastening implant adjacent the bondable material (Fig. 34); applying vibratory energy to at least the trailing end (Paras. [0447-0448]), thereby transmitting vibratory energy to the leading end to heat at least a portion of the bondable material in contact with the leading end and embed at least a portion of the leading end into the bondable material (Paras. [0447-0448]); disengaging the end effector from the trailing end (Par. [0452]), and enclosing the fastening implant in the body (Fig. 37).

Referring to claim 2, Bonutti discloses wherein the bondable material is polymethyl methacrylate (bondable material 850 or bone cement 2140; Paras. [0418], [0434] and [0455]).

Referring to claim 3, Bonutti discloses wherein at least a portion of the fastening implant (fastener 800) is bonded into the bondable material (Figs. 33-34 and Par. [0447]).

Referring to claim 4, Bonutti discloses wherein the bondable material is substantially hard before application of energy and at least a portion of the bondable material softens during the application of vibratory energy (Par. [0447]).

Referring to claim 5, Bonutti discloses wherein at least a portion of the bondable material (850; Fig. 38) flows into the fastening implant (Fig. 39) to secure the at least a portion (804) of the fastening implant to the bondable material (Figs. 38-39; Paras. [0455]).

Referring to claim 6, Bonutti discloses wherein disengaging includes rotationally disengaging the end effector (804) from the fastening implant (800; Figs. 33-34 and 37-38).

Referring to claim 7, Bonutti discloses wherein the fastening implant includes at least a portion of titanium (Par. [0206]).

Referring to claim 8, Bonutti discloses wherein the fastening implant includes at least a portion of at least one of PEEK and PLLA (Paras. [0340] and [0396-0397]).

Referring to claim 9, Bonutti discloses wherein the fastening implant includes at least a portion of titanium (Par. [0409]) and at least a portion of a polymer (the implant can be coated with a layer of bondable polymer, such as PEEK or PLLA; Paras. [0208] and [0213]).

Referring to claim 10, Bonutti discloses wherein vibratory energy includes ultrasonic energy (Par. [0201]).

Referring to claim 11, Bonutti discloses wherein the fastening implant is positioned adjacent a spine (2000; Figs. 55-56, 73 and 74A-74B) of the body to stabilize at least a portion of the spine (Paras. [0460] and [0713]).

Referring to claim 12, Bonutti discloses wherein the fastening implant stabilizes a bone (Figs. 40-40A) of a body by embedding in a previously hardened bondable material adjacent to the bone (Paras. [0193], [0235], [0343] and [0447]).

Referring to claim 13, Bonutti discloses the method of claim 1 wherein the end effector (804) is disengaged from the fastening implant when the bondable material cools and the fastening implant is left in the body (800; Figs. 33-34 and 37-38; Paras. [0339], [0349], [0368] and [0708]).

Referring to claim 14, Bonutti discloses wherein the fastening implant is positioned relative to a supporting implant, the supporting implant including a plate (plates 884, 1004, 1522 and 4100; Figs. 23, 40A, 44 and 49; Paras. [0511], [0652], [0683] and [0686]).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Referring to claim 15, Bonutti discloses a method of utilizing a bondable material (802 and 850; Figs. 34 and 38) adjacent a tissue in a body (882; Paras. [0447-0451]), said method comprising the steps of: engaging an embedding implant (800 in conjunction with screw 840; 2034 and 2008; Figs. 33 and 55-56) and an end effector (804; Fig. 33); passing the embedding implant and at least a portion of the end effector into the body (Figs. 34 and 40A); positioning the embedding implant adjacent the bondable material (the end near element 820; Figs. 33-34); applying vibratory energy to the embedding implant to embed the embedding implant into at least a portion of the bondable material (Paras. [0447-0448]); and engaging a fastening implant (840) with the embedding implant to secure the tissue (Figs. 40-40A), and enclosing the fastening implant and embedding implant in the body (Fig. 40A).

Referring to claim 16, see claim 3 above.

Referring to claim 17, see claim 2 above.

Referring to claim 18, see claim 10 above.

Referring to claim 19, Bonutti discloses wherein the bondable material has previously polymerized before positioning the embedding implant (Paras.[0343], [0447] and [0662]; embedded implant 800 can be embedded within a previously solidified bone bondable material 802).

Referring to claim 20, Bonutti discloses wherein bondable material flows around the fastening implant (stents 3500 and 3504) during application of vibratory energy (Paras. [0774]).

Referring to claim 21, see claim 5 above.

Referring to claim 22, Bonutti discloses a method of utilizing a bondable material (802 and 850; Figs. 34 and 38) adjacent a tissue in a body (882; Paras. [0447-0451]), said method comprising the steps of: engaging an embedding implant (800 in conjunction with screw 840 and 2034 and 2008; Figs. 33 and 55-56) and an end effector (804; Fig. 33); passing the embedding implant and at least a portion of the end effector into the body (Figs. 34 and 40A); positioning the embedding implant adjacent the bondable material (the end near element 820; Figs. 33-34); applying vibratory energy to the embedding implant to embed the embedding implant into at least a portion of the bondable material (Paras. [0447-0448]); positioning a supporting implant (884; Fig. 40A) adjacent the tissue; engaging a fastening implant (840) and the embedding implant to secure the supporting implant adjacent the tissue (Par. [0668]); and enclosing the fastening implant and embedding implant in the body (Fig. 40).

Referring to claim 23, Bonutti discloses wherein the embedding implant is bonded to the bondable material (Par. [0447]; embedded implant 800 can be embedded within a previously solidified bone bondable material 802).

Referring to claim 24, see claim 2 above.

Referring to claim 25, see claim 10 above.

Referring to claim 26, see claim 19 above.

Referring to claim 27, see claim 20 above.

Referring to claim 28, see claim 5 above.

Referring to claim 29, Bonutti discloses wherein the supporting implant includes a plate (plates 1522 and 4100; Figs. 23 and 49; Paras. [0511] and [0652]).

Referring to claim 30, Bonutti discloses wherein the tissue includes a bone of the body (1402; Fig. 47A).

Referring to claim 31, Bonutti discloses wherein the tissue includes at least a portion of a spine (2000) of the body (Figs. 55-56).

Referring to claim 32, Bonutti discloses a method to facilitate bonding of an implant (800 in conjunction with screw 840 and 2034 and 2008; Figs. 33 and 55-56) and bondable material (850; Fig. 38) in a body (882; Paras. [0447-0451]), said method comprising the steps of: passing the implant end at least a portion of an end effector (804; Fig. 33) into the body (Figs. 34 and 40A); positioning at least a portion the implant in bondable material (Fig. 33), the bondable material being malleable (Par. [0648]); engaging the end effector and implant (Figs. 33-34); applying vibratory energy to the implant to increase the solidification of the bondable material (Paras. [0447-0448]); and enclosing the implant in the body (Fig. 40).

Referring to claim 33, Bonutti discloses the method of claim 32 wherein the bondable material is substantially solidified while the end effector and implant are engaged (Figs. 33-34 and 37-38; Paras. [0339], [0349], [0366] and [0708]).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Referring to claim 34, see claim 2 above.

Referring to claim 35, see claim 10 above.

Referring to claim 36, Bonutti discloses which further includes the step of disengaging the end effector after the polymerization of the bondable material has been increased (Paras. [0339], [0349], [0366] and [0708]).

Referring to claim 37, see claim 20 above.

Referring to claim 38, see claim 5 above.

Referring to claim 39, Bonutti discloses wherein the implant includes an intramedullary rod (880; Fig. 40A).

Referring to claim 40, Bonutti discloses a fastening system (Figs. 33 and 55-56) implantable in a body (882; Paras. [0447-0451]), comprising: a fastening implant (800 in conjunction with screw 840; and 300; Fig. 19) including a leading end (the end near element 820; Fig. 33) and a trailing end (the end near element 810; Fig. 33), said fastening implant fabricated with a material operative to conduct ultrasonic vibratory energy from said trailing end to a portion of said fastening implant away from said trailing end (Paras. [0418], [0434] and [0456]), whereby when a portion of said fastening implant contacts a bondable material (802 and 850; Figs. 34 and 38) connected to the body and ultrasonic vibratory energy is applied to said trailing end (Paras. [0447-0448]), the bondable material attached to the body may be made flowable (Par. [0455]), and whereby after said ultrasonic vibratory energy is no longer applied to said trailing end, the bondable material may no longer be flowable, the fastening implant thereby connected to the bondable material and the body (Paras. [0447-0448] and [0455-0456]).

Referring to claim 41, Bonutti discloses the system further including the bondable material (802; Par. [0451]; Fig. 34).

Referring to claim 42, see claim 2 above.

Referring to claim 43, see claim 19 above.

Referring to claim 45, Bonutti discloses wherein said fastening implant includes a channel (810 and 844; Figs. 33 and 35) extending from an outside surface of said fastening implant to an interior of said fastening implant (Figs. 33 and 35), whereby when a portion of said fastening implant contacts a bondable material (802 and 850) connected to the body and ultrasonic vibratory energy is applied to said trailing end (Paras. [0447-0448] and [0455-0456]), the bondable material attached to the body may be made flowable and able to enter said channel (Figs. 34 and 37-39; Paras. [0447-0448] and [0455-0456]), and whereby after said ultrasonic vibratory energy is no longer applied to said trailing end, the bondable material may no longer be flowable, the fastening implant thereby connected to the bondable material and the body (Paras. [0447-0448] and [0455-0456]).

Referring to claim 46, Bonutti discloses wherein said bondable material is warmed and softened when in contact with said fastening implant and ultrasonic vibratory energy is applied to said trailing end (Paras. [0447-0448] and [0455-0456]), whereby said bondable material flows into said channel (Fig. 39), and whereby said bondable material cools and hardens after ultrasonic vibratory energy is no longer applied, said bondable material thereby becoming connected to the body and said fastening implant (Paras. [0447-0448] and [0455-0456]).

Referring to claim 47, Bonutti discloses further including an end effector (804; Fig. 33) operative to engage said fastening implant and apply vibratory energy to said fastening implant (Figs. 34 and 40A; Par. [0452]).

Referring to claim 48, Bonutti discloses further including a therapeutic implant (plate 884) connectable to said fastening implant in the body (Fig. 40A).

Referring to claim 49, Bonutti discloses further including a connecting implant (840) operative to connect said fastening implant and said therapeutic implant (Fig. 40A).

Referring to claim 50, Bonutti discloses wherein said therapeutic implant is selected from the group consisting of internal bone plate, external bone plate, spinal plate, wedge, cushion, pad, biocompatible support used for stabilization of tissue and/or implants (plates 884, 1004, 1522 and 4100; Figs. 23, 40A, 44, 49 and 74; Paras. [0511], [0652], [0663] and [0668]).

Referring to claim 51, Bonutti discloses wherein said therapeutic implant is an intramedullary device (880; Fig. 40).

Referring to claim 52, Bonutti discloses further including a bondable material (802 and 850; Figs. 34 and 38) operative to flow and connect to said fastening implant and said intramedullary device when said fastening implant is placed into contact with said bondable material adjacent said intramedullary device (Figs. 39-40 and 40A), and vibratory energy is applied to said fastening implant, said bondable material thereby operative to retain said intramedullary device and said fastening implant within the body (Paras. [0663-0664]).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Referring to claim 53, Bonutti discloses wherein said bondable materiel is malleable, and said malleability is reduced after ultrasonic vibratory energy is no longer applied to said fastening implant (Paras. [0199] and [0396-0397]).

Referring to claim 54, see claim 7 above.

Referring to claim 55, see claim 8 above.

Referring to claim 56, Bonutti discloses wherein at least a portion of said fastening implant is coated with a bondable material operative to soften upon the application of ultrasonic vibratory energy (the implant can be coated with a layer of bondable polymer, such as PEEK or PLLA; Paras. [0208] and [0213]; Figs. 48-49; Paras. [0508-0509]).

Referring to claim 57, Bonutti discloses wherein said channel extends longitudinally along an interior portion of said fastening implant (Figs. 33, 35 and 39), and is operative to contain bondable material displaced from a position exterior to said fastening implant to a position in the interior of said fastening implant (Figs. 38-39).

Referring to claim 58, Bonutti discloses wherein said fastening implant includes a metallic rod (the bondable material 850 is a rod) coated with a bondable materiel operative to soften upon the application of ultrasonic vibratory energy (Fig. 39; Paras. [0455-0456]).

Referring to claim 59, Bonutti discloses wherein said bondable material is bone cement (materiel 802; Par. [0675]).

Referring to claim 60, Bonutti discloses wherein said fastening implant further includes a widened head portion at said trailing end (Fig. 36).

Referring to claim 62, Bonutti discloses including a radiopaque marker (not shown) oriented in connection to said fastening implant to indicate a position of said channel, whereby said radiopaque marker is operative to indicate a position of said channel within the body after said fastening implant is implanted within the body, and radio imaging is applied to the body (Paras. [0388], [0760] and [0790]).

Referring to claim 63, Bonutti discloses wherein said channel contains a bondable material (Figs. 38-39; 850).

Referring to claim 64, Bonutti discloses wherein said fastening implant is an intramedullary device (Fig. 40).

Referring to claim 65, Bonutti discloses further including a connecting implant (840), said connecting implant adapted to matingly engage and connect to said fastening implant (Figs. 38-39 and 40A), said connecting implant further adapted to connect to a therapeutic implant (plate 884; Fig. 40A), said connecting implant thereby operative to connect said therapeutic implant to the body (Fig. 40A).

Referring to claim 66, Bonutti discloses wherein said connecting implant is threadably engagable to said fastening implant (Fig. 39).

Referring to claim 68, Bonutti discloses wherein said channel may contain or be filled with a therapeutic substance (Paras. [0208] and [0411-0412]).

Referring to claim 69, Bonutti discloses further including a cap (304; Fig. 19) operative to close said channel (bore 306 and anchor channel 310; Paras. [0472-0473]).

Referring to claim 70, Bonutti discloses wherein said cap is formed with a bondable material (Par. [0472]).

Referring to claim 71, Bonutti discloses wherein said cap is permeable by a material placed within said channel, and is thereby operative to permit a passage of material from said channel to the body (Par. [0472]).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Claim 61 lacks an inventive step under PCT Article 33(3) as being obvious over Bonutti.
Referring to claim 61, Bonutti discloses the system of claim 56. However, Bonutti does not explicitly disclose wherein said coating of bondable material has a non-uniform thickness along a length of said fastening implant.
However, the thickness along the length of the implant could vary depending on the application of the implant and the depth of installation. In order to create a stronger bond between the fastener and the body at the connecting point more bondable material may be utilized. The distribution of the bondable material along the length of the implant is merely a design choice and would only require routine skill in the art.
Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the bondable coating material of the fastening implant of Bonutti to include wherein said coating of bondable material has a non-uniform thickness along a length of said fastening implant, for the purpose of establishing relatively stronger bond at specific locations between the implant and the body along the length of the implant.

Claims 67 lacks an inventive step under PCT Article 33(3) as being obvious over Bonutti in view of Alacreu et al., (Hereinafter referred to as "Alacreu").
Referring to claim 67, Bonutti discloses wherein said connecting implant includes a post (middle portion of fastener 840 between threads 848 and unmarked end cap; Fig. 38), and wherein said therapeutic implant includes an aperture (the unmarked aperture of plate 884 as displayed in Fig. 40A which is similar to plate 2046 in Fig. 74B), and wherein a portion of said post is passable through said aperture (Figs. 40A and 74B). However, Bonutti does not explicitly disclose the portion of said post passing through said aperture being expandable, whereby an expanded portion of said post may be made wider than said aperture, whereby said connecting implant may be secured to said therapeutic implant.
However, Alacreu teaches a vertebral fusion system (Figs. 1 and 3) comprising a plate (4) and expandable anchoring screw (6; Fig. 1) wherein a portion of a post (the midsection of screw 6) passing through the plate aperture (16; Figs. 6-7) is being expandable (Figs. 1 and 9), whereby an expanded portion of said post may be made wider than said aperture, whereby said connecting implant may be secured to said therapeutic implant (Page 10, lines 19-25 and Page 11, lines 6-21).
Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the fastener implant of Bonutti to include the portion of said post passing through said aperture being expandable, whereby an expanded portion of said post may be made wider than said aperture, whereby said connecting implant may be secured to said therapeutic implant, as taught by Alacreu for the purpose of securely locking the post within the therapeutic plate.

Claims 1-71 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annex B).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, International Phase, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet or sheets containing a complete set of claims in replacement of all the claims previously filed must be submitted.

Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively in Arabic numerals (Section 205(a)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

SEQUENCE LISTINGS AND TABLES RELATED THERETO IN INTERNATIONAL APPLICATIONS FILED IN THE U.S. RECEIVING OFFICE

The Administrative Instructions (AIs) under the Patent Cooperation Treaty (PCT), in force as of **July 1, 2009**, contain important changes relating to the manner of filing, and applicable fees for, sequence listings and/or tables related thereto (sequence-related tables) in international applications. The complete text may be accessed at http://www.wipo.int/pct/en/texts/index.htm.

Effective **July 1, 2009**, Part 8 and Annex C-*bis* will no longer form part of the AIs. Part 8 was introduced in 2001 as a temporary solution to problems arising from the filing of very large sequence listings on paper and provided for a *sequence listing forming part of the international application* to be filed in electronic form on physical medium (*e.g.*, CD), together with the remainder of the application on paper. In 2002, Part 8 was expanded to include sequence-related tables and Annex C-*bis* was added to provide technical requirements. All applicants may now file complete international applications in electronic form, eliminating the need for these temporary provisions.

I. AIS PART 8 AND ANNEX C-*BIS DELETED AS OF JULY 1, 2009*

A) **Sequence-related tables cannot be filed as a separate part of the description or in text format.** They must be provided as an integral part of the international application either:
- in PDF format as part of an international application filed in electronic form via EFS-Web; or
- on paper as part of an international application filed on paper.

B) A *sequence listing forming part of an international application* may be provided either:
- in electronic form, as part of an international application filed in electronic form via EFS-Web, in
  - Annex C/ST.25 text format (preferred), or
  - PDF format; or
- on paper as part of an international application filed on paper.

C) A *sequence listing not forming part of the international application* **(for search under PCT Rule 13*ter*) in Annex C/ST.25 text format**
- is not required where the *sequence listing forming part of the international application* was filed in Annex C/ST.25 text format as part of an international application filed in electronic form via EFS-Web
- is required for search where the *sequence listing forming part of the international application* was filed in PDF
- is required for search on physical medium (*e.g.*, CD) where the *sequence listing forming part of the international application* was filed on paper as part of an international application filed on paper.

II. CALCULATION OF THE INTERNATIONAL FILING FEE AND FEE REDUCTION UNDER AI § 707

A) A **sequence-related table must form an integral part of the international application and will incur FULL page fees with no upper limit.**

B) A *sequence listing forming part of an international application* **filed:**
- via EFS-Web in Annex C/ST.25 text format will incur NO page fees;
- on paper or in PDF format will incur FULL page fees with no upper limit.

III. AVAILABILITY OF SEQUENCE LISTINGS SUBMITTED FOR SEARCH UNDER PCT RULE *13TER*

International Searching Authorities will be required to transmit to the International Bureau a copy of an Annex C/ST.25 text format sequence listing provided for search under PCT Rule 13*ter*. Any such sequence listing will be made available on PATENTSCOPE® (*sequence listings forming part of the international application* are already available).

IV. JULY 2009 REQUEST (PCT/RO/101)

The Request now has two options for the last sheet: one for paper filings; and one for EFS-Web filings. The July 2009 Request may be accessed at http://www.wipo.int/pct/en/forms/index.htm.